

## **ASX ANNOUNCEMENT**

**15 September 2021**

### **STRATEGY UPDATE**

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- *Sterile Readiness: Activities are nearing completion. Site audit completed by Therapeutic Goods Administration (TGA). TGA post inspection letter received, IDT response submitted. Company waiting for TGA determination on sterile licence.*
- *Australian Government Approach To Market: Proposals to establish an onshore mRNA manufacturing capability (ATM): IDT's submission to the ATM utilised the Company's brownfield sterile manufacturing facility to deliver an end-to-end, population scale, mRNA onshore manufacturing solution within 18 months. IDT is awaiting a decision from Government.*
- *Monash Institute of Pharmaceutical Sciences (MIPS) mRNA COVID-19 receptor binding protein vaccine candidate: Discussions and activities advancing with MIPS regarding IDT providing cGMP manufacturing services for Australia's first locally developed COVID-19 vaccine candidate.*
- *Australian Government Modern Manufacturing Initiative (MMI) - Manufacturing Collaboration Stream Grant Opportunity: IDT has made a submission to the \$800 million MMI Collaboration Stream Grant in its own right. The Company's submission leverages off a collaboration with Monash University, University of Melbourne, Australian National University and University of Western Australia. If successful, Grant monies will be distributed between IDT and the research institutions to fund clinical-scale capability to enable translation and commercialisation paths for Australian-based research, advancing Australia as a significant player for mRNA and gene therapies. MMI Collaboration Stream Grants may be submitted for \$20 million (minimum) to \$200 million (maximum) of grant funding; with grant funding comprising up to 33% of eligible project expenditure. Projects must have a minimum spend of \$60.6 million in eligible*

*project expenditure. Contributions from all government sources cannot exceed 65% of total eligible project expenditure and applications must have a minimum of 35% of total eligible expenditure from non-government sources. Applications closed on 9 September 2021 and Grant recipients must complete their project by 31 March 2024.*

- *Contract development and manufacturing, commercial Active Pharmaceutical Ingredients (API) and medicinal cannabis manufacturing: IDT is continuing to progress opportunities in its contract cGMP development and manufacturing, and API businesses. Contract manufacturing and new product development activities also progressing in the Company's cGMP Medicinal cannabis business.*

**IDT Australia Limited (ASX: IDT)** provides the following strategy update.

### **Sterile Readiness**

Further to the announcements made on 19 March 2021, 22 June 2021, 23 August 2021 and 15 September 2021, the Company's sterile readiness activities are nearing completion, with the TGA having conducted their site inspection of IDT's sterile manufacturing facility. IDT has received the TGA's Post Inspection Letter (PIL) and the Company's response to the PIL has been submitted to TGA for their consideration. In the absence of any further requirements from TGA, IDT is waiting to receive a sterile manufacturing licence.

### **mRNA Onshore Manufacturing Capability Approach To Market**

IDT is waiting for a decision from the Australian Government regarding the Approach To Market - Proposals to establish an onshore mRNA manufacturing capability. On 16 July 2021, IDT made a submission to the ATM which put forward the Company's brownfield sterile manufacturing facility to deliver an end-to-end population scale mRNA onshore manufacturing solution within 18 months. The Government made it clear in the ATM guidelines that any (or no) decision may be made regarding the ATM; and that the Government was also engaged in related discussions separate to the ATM process. The Government

#### **About IDT**

IDT (ASX:IDT) is an Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. The Company has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of oral and injectable finished drug dose forms.

has not provided any guidance on its decision making process and timing of same. If successful, the ATM funding will be put towards IDT delivering a population scale end-to-end mRNA sovereign manufacturing solution housed within our brownfield sterile manufacturing facility. IDT's mRNA manufacturing facility will be deployed, in the event ATM funding is secured, on an Australia-first basis to provide the country with mRNA vaccine and therapeutic content.

### **MIPS' mRNA COVID-19 Receptor Binding Domain Vaccine Candidate**

Irrespective of the ATM outcome, IDT is advancing discussions and activities with Monash Institute of Pharmaceutical Sciences (MIPS) with respect to IDT providing cGMP manufacturing services for MIPS' mRNA COVID-19 receptor binding protein vaccine candidate. The MIPS COVID-19 receptor binding domain vaccine project is already funded by mRNA Victoria and it is hoped that the initial clinical trial will commence in the fourth quarter of this calendar year. The receptor binding domain mRNA vaccine candidate has been developed by MIPS in conjunction with The Peter Doherty Institute for Infection and Immunity and is Australia's first locally developed COVID-19 vaccine candidate. If successful, the Company believes that it will be the first Australian manufactured cGMP mRNA finished product.

### **Modern Manufacturing Initiative (MMI) - Manufacturing Collaboration Stream Grant Opportunity**

On 9 September 2021, IDT made a submission to the Australian Government's \$800m Modern Manufacturing Initiative (MMI) - Manufacturing Collaboration Stream Grant Opportunity. The objective of the Australian Government's Modern Manufacturing Strategy (Strategy) is to transform Australian manufacturing by building scale and creating income in high-value areas of manufacturing where Australia either has established competitive strength or emerging priorities. Accordingly, the aims of the Strategy are to help Australian manufacturers scale-up, build resilience, compete internationally and create jobs. MMI Collaboration Stream grants may be submitted for a minimum amount of \$20 million and a maximum amount of \$200 million. With grant funding comprising up to 33% of

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eligible project expenditure, projects must have a minimum spend of \$60.6 million in eligible project expenditure. Contributions from all government sources (including Commonwealth, State and Territory and local government sources) cannot exceed 65% of total eligible project expenditure and applications must have a minimum of 35% of total eligible expenditure from non-government sources. Grant recipients must complete their project by 31 March 2024.

IDT has made this MMI Collaboration Stream Grant submission in its own right. IDT's submission leverages off a collaboration with Monash University, University of Melbourne, Australian National University and University of Western Australia. If successful, grant monies will be used to address a critical gap in clinical-scale capability to enable translation and commercialisation paths for Australian-based research, advancing Australia as a significant player for mRNA and gene therapies. Grant monies will (if the grant is successful) be distributed between IDT and the research institutions to fund a collaboration and knowledge transfer from Australia's premier mRNA research institutions to IDT which in-turn will build an mRNA translation and manufacturing ecosystem to position IDT as a Hub of Excellence in mRNA vaccine and therapeutic manufacture. This Hub of Excellence will, if IDT's grant application is successful, advance a rich pipeline of mRNA product content and put Australia at the cutting edge globally of mRNA translation and commercialisation.

### **Contract Drug Development and API Base Businesses**

In addition to the Company's sterile readiness and sterile manufacturing strategic opportunities, IDT continues to drive the contract drug development and manufacturing and commercial API base businesses. The Company is an active supporter of increased Australian sovereign manufacturing of pharmaceutical products and we are pleased to see some movement from industry away from low cost manufacturing to a focus on quality and supply chain integrity.

### **Medicinal Cannabis**

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IDT is continuing to advance its Medicinal Cannabis Manufacturing Plan. Contract manufacturing and new product development activities are progressing well in the Company's cGMP medicinal cannabis business. The Company's recently announced partnership with Clever Leaves Holding Inc. (NASDAQ: CLVR, CLVRW) to supply two varieties of medicinal cannabis flower-in-bottle is progressing. The flower-in-bottle material has now been cGMP packaged by IDT and is undergoing stability assessment. Pending the successful completion of stability trials, IDT will launch this cGMP medicinal cannabis flower-in-bottle product through Australian distributors. IDT will provide market updates in the event of any new or extended material medicinal cannabis contracts. Medicinal cannabis new product development activities are also underway, with the Company assessing and progressing several API and finished dosage form medicinal cannabis opportunities.

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## **IDT**

Authorised by the Board of Directors of IDT Australia Limited. For further information please contact:

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